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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/884,001 | 06/18/2001 | Timothy A. Bird | 2009-US | 5625 |

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| EXAMINER | |
|---|---|
| UNGAR, SUSAN NMN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/884,001 | BIRD ET AL. | |
| | Examiner | Art Unit | |
| | Susan Ungar | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *27 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) *53-58 and 60-77* is/are pending in the application.

4a) Of the above claim(s) *53-58 and 64-77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *60-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *January 15, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Amendment filed January 15, 2004 in response to the Office Action mailed July 15, 2003 is acknowledged and has been entered-in-part. Previously pending claim 59 has been canceled and Claim 60 has been amended. Claim 60-63 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. It is noted that the amendments to the specification beginning at page 9, line 23 and beginning at page 15 line 18 are non-responsive to the Rules since there is no indication in the amendments as to what has been amended, neither underlining nor bracketing is disclosed. However, in the interests of compact prosecution, Examiner is not holding the amendment non-responsive, rather the requested amendments drawn to pages 9 and 15 have not and will not be entered. If Applicant desires to amend the specification, it is suggested that new amendments that adhere to the Rules be submitted.

4. The following objections are maintained:

Objection to the specification drawn to typographical errors recited in Section 4 of the previous action and objection to the sequences in Section 5 of the previous action is maintained because appropriate correction was not made.

5. The following rejections are being maintained:

***Claim Rejections - 35 USC § 101***

6. Claims 60-63 remain rejected under 35 USC 101 for the reasons previously set forth in the paper mailed July 15, 2003, Section 8, pages 4-7.

Applicant argues that (a) the claimed invention, a sGNK polypeptide, has a well established utility, i.e. for use in the regulation or treatment of angiogenesis or vasuclarization, (b) the claimed invention is specific because it is a physiological

substrate of GNK a kinase which is known to play a critical role in angiogenesis and vascularization, (c) the utility of the claimed invention is credible unless the logic underlying the assertion is seriously flawed or the facts upon which the assertion is based are inconsistent with the logic underlying the invention, (d) the specification discloses the role of GNK in vascularization in Figure 11 which clearly shows that vascularization is greatly reduced in the yolk sacs from mice that are deficient of GNK and thus the logic underlying the utility assertion is neither seriously flawed nor inconsistent with the facts and the asserted utility is substantial because it defines a real world use since the utility is connected to angiogenesis and vascularization regulation

The arguments have been considered but have not been found persuasive because (a') for the reasons of record the neither the art of record nor the specification as originally filed establishes that the claimed invention can be used in the regulation or treatment of angiogenesis or vascularization, (b') although GNK phosphorylates sGNK and sGNK is a newly identified substrate of GNK, numerous other unrelated substrates for GNK were known including mammalian beta caseins, hsp27 and symthetic peptide substrates (as disclosed in the newly submitted WO97/47750). Further, the consensus sequence that GNK phosphorylates is known in the art, thus, it is expected that a large number of polypeptides which are at this time unknown, share the known consensus sequence and are also substrates of GNK. The fact that sGNK shares this consensus sequence with other polypeptides does not provide a specific utility for the claimed invention, thus this is not considered a "specific" utility of sGNK, further, this is not a substantial utility since additional work must be done in order to determine a function for the phosphorylated invention, (c') for the reasons of record, the

asserted utility of the claimed invention is not credible, (d') for the reasons of record it has not been established that sGNK, an apparent phosphorylation substrate for GNK, is in any way associated with angiogenesis or vascularization or what that association may be and further experimentation is required in order to establish a real world use for the claimed invention.

Applicant further argues that it is not proper that; (e)(1)Examiner requires a showing in human of the data in Figure 10 and (e)(2) Examiner states that the asserted utility is not supported by the degree of sequence homology between human sGNK and bicaudal-D protein and human c-Nap-1, because the rejections are not based on evidence that one would doubt the asserted utility and they are merely allegations based on Examiner's knowledge of science and patent law given the Applicant's disclosure, (f) although Examiner has established that the role of bicaudal-D protein is in cytoskeleton, mRNA sorting and polarity of developing embryo and the specification teaches that sGNK is associated with vascularization and angiogenesis, this does not establish that the role of the claimed invention are inconsistent. sGNK may function to regulate cytoskeletal dynamics that affect endothelial cell growth, migration or adhesion, processes that are known to be involved with vascularization and Examiner has failed to demonstrate that the logic underlying the asserted utility is seriously flawed or that the facts are inconsistent with logic and has failed to provide evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility, (g) Examiner cannot make this type of rejection unless she has reason to doubt the objective truth of the applicants' statement in the specification and thus the only reasonable conclusion that could be reached based on the applicants' disclosure is that the asserted utility is well established.

The arguments have been considered but have not been found persuasive because (e')(1) Applicant has mischaracterized Examiner's rejection, Examiner never required a showing of human data, rather, the lethality of the GNK-minus mutation in mice raised the question of whether or not the animal model would be correlative to the human condition. In particular Examiner stated that "it is not possible to correlate this information with the utility of the instant invention", (e)(2) the asserted utility is not supported by the sequence homologies for the reasons of record, the rejection is based on sound scientific reasoning and given that reasoning no one would believe it more likely than not that the claimed invention would function as asserted based on the homology of the claimed invention to bicaudal-D protein and human c-Nap-1, (f') Applicant's opinion of what sGNK "may" do does not support the utility of the claimed invention and for the reasons of record the claimed invention does not meet the requirements of 35 USC 101, (g') for the reasons of record no one of ordinary skill in the art would believe it more likely than not that the claimed invention has a well established utility. Applicant's arguments have been considered but have not been found persuasive and the rejection is maintained.

***Claim Rejections - 35 USC § 112***

7. Claims 60-63 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed July 15, 2003, Section 10, page 8.

Applicant reiterates arguments set forth above. The arguments have been considered but have not been found persuasive for the reasons set forth above and the rejection is maintained.

8. Claims 60-63 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed July 15, 2003, Section 11, pages 8-13.

Applicant states that Examiner has mischaracterized the claims wherein Examiner has not included the functional limitations of item (1) (disclosed in the response) with the disclosed items (2) and (3) (also in the response) in the Examiner's statement of the claims recited in the paper mailed July 15, 2003. Applicant states that Applicants will respond to Examiner's rejection in view of these limitations. Examiner apologizes for any impression of a mischaracterization or lack of clarity in the statement of the claims on page 8 of the paper mailed July 15, 2003 due to the brevity of Examiner's summary, however, it is clear from the body of the rejection that the rejection is drawn to the enablement of the binding to and/or phosphorylation of the claimed variants by GNK.

Applicant reiterates the Wands requirements for enablement and state that the Wands requirements are satisfied. Applicant argues that (a) applicant's teach a wide variety of variants that include polypeptides that are at least 80% identical to SEQ ID NO:2 and how to make them and teaches an assay for the phosphorylation of sGNK by GNK, (b) the cited publications are not applicable since the polypeptide variants have limitations that are specific to sGNK that can be determined by the teaching of the specification while the cited references individually discuss either an unknown protein or a protein which is not related to sGNK. The arguments have been considered but have not been found persuasive because (a') the specification does not teach how to make and use the claimed invention commensurate in scope with the claims and the assay which demonstrates that sGNK is phosphorylated by GNK is not sufficient to enable the

claimed invention, (b') although the references are not specific to the claimed invention, they clearly demonstrate the state of the art at the time the invention was made and for the reasons of record the scope of the claimed invention is not enabled. It is noted that Applicant has not addressed the issues raised drawn to polypeptides encoded by moderately hybridizing polynucleotide, the teachings of Scott et al, the teachings of Bork. The arguments have been considered but have not been found persuasive and the rejection is maintained.

9. Claims 61 and 63 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed July 15, 2003, Section 11, pages 13-14.

Applicant argues that (a) the claimed fragments should be considered to be additional to the fragments that are disclosed in the specification. This is supported by the stated that "also provided herein are polypeptide fragments comprising at least 20 and about at least 30 contiguous amino acids", (b) based on the reasons stated by the Examiner to support this rejection, the rejection appears to be more of a new matter rejection, not a written description-type rejection and if that is the case, Examiner has not made a *prima facie* case of lack of written description by presenting evidence or reasons why one skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. The arguments have been considered but has not been found persuasive because (a') the specification does not support the suggested "additional" broadened limitations. The specification is quite clear in the teaching that polypeptide fragments are drawn to polypeptide fragments comprising at least 20 and about at least 30 contiguous amino acids, (b') Applicant is correct, the rejection as stated is a "new matter" rejection. Examiner clearly disclosed that a review of the

specification revealed support for fragments of SEQ ID NO:2 comprising at least 20 or at least 30 contiguous amino acids of SEQ IDNO:2 at page 14 but that there was no support for the broadly worded claims and that the claims as written broadened the scope of the invention as originally disclosed in the specification, thus both evidence and reasons why one skilled in the art would not recognize in the disclosure a description of the invention defined by the claims has been presented. Applicant's statement that the claimed fragments should be considered to be additional to the fragments that are disclosed in the specification clearly demonstrates that support for the broadly worded limitations is not found in the specification as originally filed.

***Claim Rejections - 35 USC § 102***

10. Claims 60-61 remain rejected under 35 USC 102(a) for the reasons previously set forth in the paper mailed July 15, 2003, Section 13, pages 14-15.

Applicant argues that the Declaration under 37 CFR 1.131 overcomes the rejection under 35 USC 102(a). The argument has been considered but has not been found persuasive because the Declaration is not commensurate in scope with the claims as currently constituted since it is drawn only to the complete sequence of SEQ ID NO:1 which encodes SEQ ID NO:2 and the scope of the claims are not limited to the complete sequence of the polypeptide encoded by SEQ ID NO:1. In particular, the rejection is based on Applicant's claims to polypeptides encoded by polynucleotides that hybridize under moderately stringent conditions and sequences at least 80% identical to SEQ ID NO:2. The prior art reference meets the limitations of the claims for the reasons of record, is not drawn to a sequence with 100% identity to SEQ ID NO:2 and the Declaration under 35 CFR 1.131 is not sufficient to overcome the rejection under 35 USC 102(a). It is noted that,

contrary to Applicants statement, the Exhibit found in the file does not set forth the amino acid sequence of SEQ ID NO:2. The argument has been considered but has not been found persuasive and the rejection is maintained.

***Claim Rejections - 35 USC § 103***

11. Claim 63 remains rejected under 35 USC 103 for the reasons previously set forth in the paper mailed July 15, 2003, Section 15, pages 16-17.

Applicant argues that since the primary reference is not a proper reference and has been antedated by the Declaration under 1.131, the Yoon et al reference is not sufficient by itself to support a rejection under 35 USC 103.

The argument has been considered but has not been found persuasive because the Declaration under 1.131 is not sufficient to antedate the prior art reference for the reasons set forth above, and for the reasons of record, the claimed invention is obvious over the Ishikawa et al and Yoon et al references in combination. The argument has been considered but has not been found persuasive and the rejection is maintained.

12. All other objections and rejections recited imposed in the paper mailed July 15, 2003 are hereby withdrawn.

14. No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT

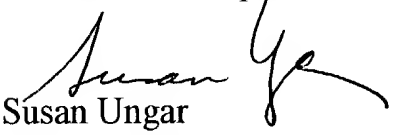
TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvette Eyler, can be reached at 571-272-0871 The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.



Susan Ungar
Primary Patent Examiner
March 25, 2004